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A study of compost workers in four cities indicated only relatively minor effects in workers within 100 m of composting operations. The observed effects may have been due to irritants produced in the composting process (dust, Aspergillus) and not related to the sludge portion of the compost. A prospective epidemiological study concerning the land application of sludge indicated no significant differences in illness and infection rates of people and animals on sludge-applied farms as compared to control farms. However, the human exposure to sludge was very low. The continued use of comprehensive, agent-based prospective epidemiological studies to assess the pathogenic risk of sludge disposal options (with the possible exception of D&M) is not recommended because of design, interpretation and site-specificity problems and because of cost considerations. Disease-based surveillance systems may be of some value in identifying hazardous disposal practices and further investigation into the design and implementation of such systems is recommended. Modeling may be a viable approach for assessing the risk of sludge disposal options but much more work needs to be done to evaluate and validate existing models and to possibly develop alternate models.

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INTRODUCTION

Approximately 6.5 million dry tons of municipal wastewater sludge are now generated annually in the United States and this quantity is expected to about double by the year 2000.[1] In order to protect the public health and the environment, good management practices are necessary for the major disposal options utilized in this country--land application, distribution and marketing, landfilling, incineration and ocean disposal. Developing rational guidelines for good management practices requires assessing the risk of potential hazards associated with the disposal options. A potential hazard exists with respect to pathogens because viable bacteria, viruses, parasites and fungi have been and can be detected in municipal wastewater sludges. Determining the significance of the potential pathogen hazard involves quantifying the risk.

Epidemiological investigation is one possible approach to quantifying risk. Epidemiology has been defined by Lilienfeld[2] "...as the study of the distribution of a disease or a physiological condition in human populations and of the factors that influence this distribution." Factors relative to the disease or condition and the time, place and person must be identified and described. Through an examination of statistical associations, inferences may be derived on the etiology of the disease and possible preventive measures may be identified.

There are almost as many different types of epidemiological studies as there are epidemiologists. However, a useful generalization is to divide all epidemiological studies into two major types--retrospective and prospective. In a retrospective study, the disease or condition has already occurred and details are obtained from historical records. In a prospective study, relevant characteristics pertaining to time, place and person are identified at the outset of the study and disease is recorded as it occurs. Prospective studies are usually considered to produce stronger associations than retrospective studies since all relevant characteristics may not be available in the historical record. The purpose of this paper is to review two prospective epidemiological studies of sludge treatment and disposal and to discuss some methodological problems and limitations of the epidemiological approach.

COMPOST WORKER STUDY

A prospective epidemiological study was conducted of workers at wastewater sludge composting facilities in four cities--Camden, NJ, Philadelphia, PA, Washington, DC and Beltsville, MD--between 1979 and 1981.[3-5] There were five composting facilities, all utilizing a thermophilic aerated pile process. They received sludge from six primary and secondary wastewater treatment plants ranging in size from 4 to 300 million gallons per day (mgd). The composting facilities ranged in size from 15 dry tons of compost per day (dtd) in Camden and Beltsville to 125 dtd in Philadelphia.

A total of 388 compost and control workers were divided into three exposure categories: high--98 workers directly engaged in composting; intermediate--157 workers occasionally involved with composting or having job locations within 100 m of a composting operation, and low--133 workers not involved in compost activities and with job locations greater than 100 m from the sites. Clinical and serologic evaluation included illness monitoring with 30-day recall; physical examinations and chest x-rays; nasal and throat cultures; pulmonary function tests; antibody testing to fungi, Legionella, histoplasma and endotoxin; immunochemical testing, and routine blood analyses. Clinical specimens (nose and throat cultures, sera) and health questionnaires were collected eight times during the study period. Environmental monitoring involved air sampling and analyses for Aspergillus fumigatus and other thermophilic fungi.

The illness questionnaires were analyzed by illness group (total, upper respiratory, lower respiratory, non-respiratory, diarrhea, skin irritation, burning eyes), worker category and compost plant location. The only symptoms for which there was the suggestion of a pattern associated with compost exposure were burning eyes and skin irritation. More of these symptoms were reported by the high and intermediate exposed workers. Physical examination showed that more high and intermediate-exposed workers had acute or chronic inflammation of the eyes and nose, evidence of ear infection and skin conditions. However, the investigators indicated that these results should be interpreted with caution because of the relatively small number of workers involved, geographic differences in nasal disorders and because the intermediate-exposed workers had a similar or higher proportion of disorders than did the high-exposed category of compost workers. The prevalence of positive A. fumigatus cultures from the anterior nares and throat swabs was consistent with the exposure designations--70% from the high, 20% from the intermediate and 5% from the low categories. Results of the pulmonary function tests indicated that compost workers had a higher forced vital capacity on Friday evening as compared to Monday morning, suggesting that non-exposure to compost over the weekend may have been a factor. However, the investigators could not explain this result and they pointed out that the opposite effect would have been expected with weekend absence from a pulmonary irritant. No consistent increase in antibody to A. fumigatus was detected but compost workers had the highest IgG antibody levels against compost-derived endotoxin. Antibodies to Histoplasma capsulatum were not detected and there was no difference among exposure groups in antibody to Legionella pneumophila. The routine blood tests showed

higher white cell and eosinophile counts in compost workers and this was consistent with immunochemical tests (elevated C3 and hemolytic complement levels), which suggested that these workers may have experienced a low-grade inflammatory response. In summary, workers within 100 m of composting operations may have experienced some minor effects. However, these effects were not of an infectious nature and may be the result of exposure to irritants (dust, endotoxins, Aspergillus) produced during the composting process rather than being related to the pathogen content of the sludge.

OHIO FARM FAMILY STUDY

A five-year study was funded by the U.S. Environmental Protection Agency (USEPA) and conducted by the Ohio Farm Bureau Development Corporation with two major objectives: (1) to define and demonstrate management systems for application of sludge to farmlands which would minimize adverse impacts on the rural community, and (2) to evaluate the health risks to rural residents and their livestock resulting from the application of sludge to cropland.[6] The second objective was addressed through a prospective epidemiological study of farm residents in four counties (Franklin;, Pickaway, Medina, Clark) located in northeastern and central Ohio. Annual surface applications of liquid or dewatered anaerobically or aerobically digested sludges were made at rates of 2-10 dry metric tons/ha. Most of the applied sludge came from the City of Columbus and consisted of anaerobically digested sludge dewatered to a solids content of 17-20%. Sludge was spread on selected fields or parts of fields and the average size of the sludge-applied area ranged from 15 to 47 ha. The principal crops grown were corn, soybeans, wheat and hay.

The study population consisted of 164 persons (78 families) on 47 farms receiving sludge, and 130 persons (53 families) on 46 control farms. Participants completed monthly questionnaires on illness symptoms for themselves and their animals (livestock and pets). A panel consisting of two infectious disease specialists, a toxicologist and an epidemiologist grouped the human data into the following categories: (1) general--fever, headache or generalized muscular aches and pains; (2) digestive--nausea or diarrhea; (3) upper respiratory--runny nose, sore throat, nasal congestion or hoarseness, and (4) lower respiratory--chest congestion or cough. A panel consisting of a veterinary clinician and an epidemiologist grouped the animal symptoms and signs into two categories: (1) digestive--constipation, diarrhea or blood in feces, and (2) respiratory--cough, nasal discharge or difficult breathing.

Baseline blood samples were collected before the first application of sludge and every four months afterwards. Serum specimens were tested for antibodies to 23 different coxsackie and echoviruses and to hepatitis A. Fecal specimens were also collected every four months and were analyzed for bacterial, viral and parasitic pathogens. Tuberculin testing was performed annually. Fecal specimens from grazing cattle on four sludge and four control farms were examined for bacterial and parasitic pathogens over a three-year period. Tuberculin tests were performed on calves that were slaughtered after grazing for three to eight months on sludge-applied

pastures. Soil and forage samples were collected over a one-month period for parasite analysis from sludge-treated and untreated pastures on three farms. Sludge samples were collected bi-weekly from four sewage treatment plants supplying the sludge to the farms and these samples were analyzed for bacteria, viruses and parasites.

All farms completed at least one year of participation; 36 and 37 sludge and control farms, respectively, completed two years, and 13 each of the sludge and control farms completed three years of participation in the health effects study. Approximately 13% of field work was performed on sludge-applied land over all seasons. About 38% of participants on sludge farms had an exposure to sludge of 0-10 minutes/week; about 40% were exposed for 10-90 minutes/week, and about 21% had an exposure greater than 90 minutes/week.

A total of 307 treatment plant sludge samples were examined for viruses and 69% (211) of these yielded one or more viruses. There were 25 different enterovirus serotypes isolated and the most common, in decreasing order of occurrence, were echo 7, coxsackie B3, polio 2 and echo 24. These four viruses accounted for about 59% of the viruses isolated from sludge. Fourteen of the isolated serotypes were included in the battery of 23 antigens used for antibody testing of participant sera. Salmonellae were isolated from 16% (50/311) of the sludge samples with Salmonella infantis, saint paul, typhimurium and agona being the most frequently isolated species. No shigellae or Campylobacter were detected in sludge samples. Only ova of Toxocara were detected in five of 82 sludge samples examined for parasites. Examination of soil and forage samples from sludge-applied fields revealed only one ascarid ovum (Ascaris or Toxocara) in a forage sample collected 14 days after sludge application.

Health questionnaires were analyzed for illnesses occurring over the total duration of the study and by the three-month period immediately following sludge applications. There were no significant differences in respiratory and digestive illnesses or in general symptoms between the sludge farm and control farm residents. In the serological analyses, 124 infections (4-fold or greater increase in antibody titer) were detected in 67 people--69 infections in 34 people on sludge farms and 55 infections in 33 people on control farms. The infections were about equally distributed between coxsackie and echoviruses. Logistic regression analysis of the serological conversions on paired farms after the first and second applications of sludge and for the entire study period indicated that exposure to sludge was not related to differential increases in antibody titer. Only eight rises in antibody titer to Salmonellae were detected and these were evenly distributed between sludge-exposed and control participants. No participants converted from tuberculin-negative to positive after sludge application and there were no seroconversions to hepatitis A over the period of the study. There was no significant difference in the frequency of virus detection in stool specimens of participants between sludge and control farms--16 viruses from 15 people on sludge farms and 9 viruses from 9 people on control farms. Neither shigellae nor parasites were detected in human stools from both sludge and control farms. Salmonellae were isolated from four individuals, three from

sludge farms and one from a person on a control farm. The health of domestic animals did not differ between sludge and control farms. Four control and two sludge farm animal fecal samples were positive for Salmonellae. There was no significant bacterial or parasite health risk to animals on sludge farms and tuberculin tests of calves grazing on sludge-applied pastures were negative.

In summary, this study did not identify human or animal pathogen health effects resulting from the application of sludge to farmland at rates in accordance with Ohio and USEPA guidelines. However, the exposure of most of the participants on the sludge farms was very low. The investigators indicated that caution should be used in applying these data to predict health risks associated with sludges containing high levels of pathogens and with higher application rates and larger acreages treated per farm.

DISCUSSION

Epidemiological studies can be helpful in determining the etiologic agent of a disease and in evaluating the significance of a potential hazard, i.e., quantifying the risk. The etiologic agents in sewage sludge, and the diseases or symptoms that they cause, are already known. What is needed is a method for quantifying the risks associated with the disposal of sewage sludge.

Traditional infectious disease epidemiology uses the symptoms, syndrome or disease as a starting point. The disease or syndrome is clearly recognized, an historical example being cholera and more recent examples being giardiasis, Legionnaires' Disease and acquired immune deficiency syndrome (AIDS). The recognition of the disease usually comes about as the result of an outbreak or clustering of cases to the extent that the disease becomes noticed either by the public at large or by health authorities. Once recognition has occurred, then information is gathered on the characteristics of person, place and time and associations are developed.

Strict definition of the disease is sometimes difficult, even if the etiologic agent is known. In the examples given above, cholera and giardiasis are both characterized by diarrhea and Legionnaires' Disease is a pneumonia. Pathogens other than Vibrio cholerae and Giardia lamblia can cause diarrhea, and penumonia is usually caused by organisms other than Legionella. In addition, many pathogens produce a spectrum of effects ranging from asymptomatic to debilitating disease and death. When investigating an infectious disease, it is necessary to develop a clear case definition that may include differential diagnosis based on isolation of the organisms from clinical specimens.

In contrast to the traditional infectious disease epidemiological approach are the USEPA-funded studies of pathogenic health effects from exposure to wastewater and sludge.[7-9] Sewage and sewage sludge contain a myriad of pathogens capable of producing a wide variety of diseases and a specific disease was not under investigation in these studies but rather, the occurrence of a wide variety of symptoms in the exposed populations. Consequently, investigators

usually collapsed reported symptoms into three broad categories--respiratory, gastrointestinal and other (fever, headache, etc.). There are several potential confounders in this approach: the production of these symptoms is not limited to infectious agents found only in sewage, e.g., influenza is not a sewage-borne organism but it can cause these symptoms; the transmission of the agents is not limited to sewage as an exposure vehicle--they can be transmitted by person-to-person contact, food and water as well; reporting of the symptoms may be biased by the perception of the respondent of the benefit to be derived by over- or under-reporting or affected by the length of recall required by the survey instrument, and it may be difficult to classify or impossible to quantitate the exposure received by the participants.

These problems are not insurmountable and they have been addressed by incorporating objective measures of response, such as isolation of pathogens from clinical specimens and examination of serological response to selected agents. In addition, environmental monitoring may be incorporated to quantitate the level of exposure. However, these solutions are not without their own problems in that they require a high level of cooperation on the part of volunteers in providing fecal and blood samples and quantitative methods are not available for determining the level of many of the pathogens in air, water, wastewater, sludge or other potential routes of exposure. Another factor that must be considered is the cost of these solutions. Of the 11 epidemiological studies funded by USEPA, eight of these have been prospective in design and they required an average of $1,000,000 each to perform.[9]

The recommendations of expert groups on conducting epidemiological studies of exposure to pathogens in wastewater and sludge have been changing over the last 12 years. At a workshop held in Champaign, IL in 1973, a panel on the public health aspects of recycling municipal sludges and effluents on land gave their first priority to "...comprehensive epidemiologic studies on human populations associated with both new and long-established land disposal systems."[10] They indicated that studies should be done on sewage plant workers and their immediate families with the objective of providing reliable data for developing regulations. Nine of the previously mentioned 11 studies have been completed and they have involved sewage treatment plant employees and their families as well as populations living in the vicinity of activated sludge sewage treatment plants and spray irrigation sites. These nine studies found either no or insignificant pathogen health effects; final results are not yet available on two studies of spray irrigation of wastewater. While the studies were useful in addressing citizen concerns, they have been of little value in developing regulations for treatment and disposal.

A 1979 WHO report on viruses in water, wastewater and soil indicated that current epidemiological techniques are not sensitive enough to detect low-level transmission of viruses through water.[11] However, another WHO working group on the health risk of microbes in sludge applied to land recommended in 1981 that "Carefully planned epidemiological investigations into the relationship between sludge

spreading and the public health should be encouraged."[12] In 1983, a panel on public health and risk assessment of pathogens in wastewater and sludge indicated that epidemiological studies should not remain as the highest research need but that some studies of high exposure populations may be appropriate.[13] A workshop in Cincinnati in 1984 concluded that epidemiological studies of populations exposed through various sludge disposal options would be very expensive, lengthy and have a low probability of producing interpretable data.[14] However, distribution and marketing (D&M) was identified as one sludge disposal option where the epidemiological approach might be applicable because of the intimate contact users have with the product through use in home gardens and flower pots. Similar conclusions were reached by participants at a workshop in Metz, France in May 1985 sponsored by the Commission of European Communities (CEC).[9] All four panels at the workshop independently concluded that prospective epidemiological studies of sludge-exposed populations should not now be conducted because of design, interpretation and expense considerations. All four panels did recommend the development and implementation of surveillance programs, and the need for additional information on the health effects of composted sludge products was expressed.

It does not appear likely that prospective epidemiological studies will be a viable approach to developing quantitative risk assessment for most sludge disposal options (D&M may be an exception) due to the problems of identifying suitably exposed populations and of quantifying that exposure. In addition, even if the resources were available, and prospective epidemiological studies were conducted involving sludge subjected to different treatment disposal processes, no matter what the outcome of those studies they would probably not be useful in developing national guidelines for safe disposal. The studies would necessarily be site-specific and the extrapolation of results to other sites with different conditions for pathogen transport and survival and different exposure routes would be questionable.

How, then, can risk assessment be done? There are those who feel that the negative results of the studies reported to date and the lack of outbreaks associated with wastewater and sludge treatment and disposal activities indicate that there is little or no problem with infectious disease from this exposure. There are others who feel that the low exposure and small populations in the reported studies precluded positive findings and that the inadequacy of surveillance systems would allow disease associated with pathogens in sewage to go undetected. In 1976, Hoadley and Goyal described the reporting of cases of enteric disease as "notoriously poor" and they suggested that surveillance of disease in humans and animals, and surveillance of the environment, should be undertaken as part of land application systems for wastewater.[15] They did not elaborate on the form, content or scope of the surveillance activities; neither did the CEC panels that recommended surveillance of sludge disposal practices in 1985.[9] Disease-based surveillance would be a return to the traditional epidemiological approach in that it would be starting with occurrence of the disease instead of with occurrence of the agent. It would probably be advisable to initiate such activities by selecting diseases of primary concern that could

be clearly defined and recognized, e.g., hepatitis A and parasitic infections. An appropriate surveillance network might then reveal trends and pinpoint disposal practices or situations requiring in-depth epidemiological investigation.

Another approach to risk assessment involves mathematical modeling. Modeling is attractive because site-specific assessments may be developed. Disadvantages to modeling include the quantity and variety of data that might be necessary to approximate real-world conditions and the uncertainty factor that would reflect the quality of the data and what we think we know concerning the important characteristics of pathogen fate, transport and infection coupled with estimations of exposure. At least two models have been developed for assessing the risk of sludge disposal. A relatively simple model was constructed and used by Seattle Metro to assess risk of sludge disposal by silviculture.[16] A much more complex model was developed by BDM Corporation.[17] Neither of these models has been validated but evaluation of both of them, and consideration of other models, is currently in progress.[18]

SUMMARY

1. A study of compost workers in four cities indicated only relatively minor effects in workers within 100 m of composting operations. The observed effects may have been due to irritants produced in the composting process (dust, Aspergillus) and not related to the sludge portion of the compost.

2. A prospective epidemiological study concerning the land application of sludge indicated no significant differences in illness and infection rates of people and animals on sludge-applied farms as compared to control farms. However, the human exposure to sludge was very low.

3. The continued use of comprehensive, agent-based prospective epidemiological studies to assess the pathogenic risk of sludge disposal options (with the possible exception of D&M) is not recommended because of design, interpretation and site-specificity problems and because of cost considerations.

4. Disease-based surveillance systems may be of some value in identifying hazardous disposal practices and further investigation into the design and implementation of such systems is recommended.

5. Modeling may be a viable approach for assessing the risk of sludge disposal options but much more work needs to be done to evaluate and validate existing models and to possibly develop alternate models.

NOTICE

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